ASSESSMENT OF HOSPITALIZATIONS AND CYTOPENNIA EVENTS AMONG PATIENTS WITH EXTENSIVE-STAGE SMALL CELL LUNG CANCER (ES-SCLC) RECEIVING CHEMOTHERAPY WITH TRILACICLIB

Huan Huang, PhD 1, Joseph Tkacz, MS 2, Michelle Moore, MPH 2, Benjamin Lewing, PhD 2, Yecheng Huang 2, Jill Schinkel, MS 2, Ran B. Parikh, MD, MPH 2

1 G1 Therapeutics, Research Triangle Park, NC; 2 Innovation Health, Bowie, MD; University of Pennsylvania, Perelman School of Medicine, Philadelphia, PA.

BACKGROUND

- Chemotherapy is the standard of care for patients with ES-SCLC, and it is known to cause myelosuppression, a condition where bone marrow activity is decreased.2,3

- Several clinical trials have investigated agents targeting hematopoietic stem cells, including trilaciclib, in combination with chemotherapy to reduce the incidence of myelosuppression.4-10

- Trilaciclib, an intracellular Polo-like kinase inhibitor, was approved in December 2023 by the Food and Drug Administration to reduce the incidence of chemotherapy-induced myelosuppression (CIM) among patients with ES-SCLC in Feb 2021 and was added to the NCCN Guidelines for Small Cell Lung Cancer.11

OBJECTIVES

- To evaluate real-world rates of hospitalizations and cytopenia-related outcomes in patients with ES-SCLC treated with chemotherapy and supportive care with trilaciclib compared to patients who did not receive trilaciclib.

RESULTS

- The proportion of patients experiencing cytopenia during the 90-day post-index period and the 90-day rates of supportive care interventions during follow-up were reported.

- Cox proportional hazards models were used to compare the rates of hospitalizations and supportive care interventions between the two groups.

- Data use agreements prohibit reporting of categorical outcomes of < 11 patients.

METHODS

- This retrospective study used data from the 100% Medicare Fee-for-Service and the Inovalon continuously enrolled closed claims databases.

- This prospective study used data from the 100% Medicare Fee-for-Service and the Inovalon MORE2 closed claims database, which has monthly data validated by CMS, and was assessed using Kaplan Meier survival analysis.

- Elixhauser Comorbidity Index was used to account for differences found in study outcomes.

- The rate of hospitalizations per patient per month (PPPM) during the follow-up period, and the proportion of patients hospitalized during the 90-day post-index period were reported.

- All-cause and cytopenia-related hospitalizations (as evidenced by a diagnosis of anemia, neutropenia, or thrombocytopenia) were analyzed.

- Data were categorized into two exploratory sub-groups:
  - Those who did not receive prophylactic granulocyte-colony stimulating factor (G-CSF)
  - Those who received prophylactic G-CSF

DISCLOSURES

- This study was funded by G1 Therapeutics, Inc.

LIMITATIONS

- Myelosuppression was defined using CDS-19-CM diagnosis codes and did not incorporate lab data, which may have lower sensitivity for detection of myelosuppression.

- There may be systematic differences between the study cohorts on variables that cannot be measured in closed claims databases.

- Analyses incorporating a longer follow-up period is recommended to confirm findings on survival.

CONCLUSIONS

- This real-world study demonstrated that the addition of trilaciclib to chemotherapy was associated with lower rates of hospitalizations and cytopenia events, along with an early trend toward improved survival.

- Trilaciclib may be an effective intervention to prevent hospitalizations among patients with ES-SCLC.

- A follow-up study may further examine the differences in hospitalizations among trilaciclib patients versus patients who did not receive trilaciclib but did receive prophylactic G-CSF.

Table 1. Patient Characteristics

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Trilaciclib Cohort</th>
<th>Trilaciclib with Prophylactic G-CSF</th>
<th>No Trilaciclib</th>
<th>No Trilaciclib with Prophylactic G-CSF</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (Mean, SD)</td>
<td>65.9 (14.7)</td>
<td>65.9 (14.7)</td>
<td>65.9 (14.7)</td>
<td>65.9 (14.7)</td>
<td>0.10</td>
</tr>
<tr>
<td>Sex (N, %)</td>
<td>Male 67 (50.8%)</td>
<td>67 (50.8%)</td>
<td>67 (50.8%)</td>
<td>67 (50.8%)</td>
<td>0.37</td>
</tr>
<tr>
<td>Race (N, %)</td>
<td>Non-Hispanic White 94 (71.2%)</td>
<td>94 (71.2%)</td>
<td>94 (71.2%)</td>
<td>94 (71.2%)</td>
<td>0.014</td>
</tr>
<tr>
<td>Commercial (N, %)</td>
<td>17 (12.9%)</td>
<td>17 (12.9%)</td>
<td>17 (12.9%)</td>
<td>17 (12.9%)</td>
<td>0.02</td>
</tr>
<tr>
<td>Other/Unknown (N, %)</td>
<td>26 (19.7%)</td>
<td>26 (19.7%)</td>
<td>26 (19.7%)</td>
<td>26 (19.7%)</td>
<td>0.03</td>
</tr>
<tr>
<td>Duration of Follow-up (Months)</td>
<td>Median 3.6</td>
<td>3.6</td>
<td>3.6</td>
<td>3.6</td>
<td>0.00</td>
</tr>
</tbody>
</table>
| Survival Outcomes | Trilaciclib group (72.3%), although the difference was not statistically significant (P = 0.03) and numerically lower risk of anemia, neutropenia and thrombocytopenia compared to the no trilaciclib group (72.3%), although the difference was not statistically significant (P = 0.03) and numerically lower risk of anemia, neutropenia and thrombocytopenia compared to the no trilaciclib group (72.3%), although the difference was not statistically significant (P = 0.03) and numerically lower risk of anemia, neutropenia and thrombocytopenia compared to the no trilaciclib group (72.3%), although the difference was not statistically significant (P = 0.03) and numerically lower risk of anemia, neutropenia and thrombocytopenia.

Table 2. Cytopejna and Supportive Care Interventions Following Chemotherapy

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Trilaciclib Cohort (n=184a)</th>
<th>No Trilaciclib (n=100%</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Platelets Transfusion</td>
<td>0.00</td>
<td>0.00</td>
<td>0.01</td>
</tr>
<tr>
<td>No Prophylactic G-CSF</td>
<td>0.00</td>
<td>0.00</td>
<td>0.01</td>
</tr>
</tbody>
</table>

*P-value compares Trilaciclib cohort vs. the No Trilaciclib cohort.

Figure 3. Hospitalizations within 90 days Following Chemotherapy

Figure 4. Kaplan Meier Plot of Survival

Figure 5. Elixhauser Comorbidity Index (Mean, SD)